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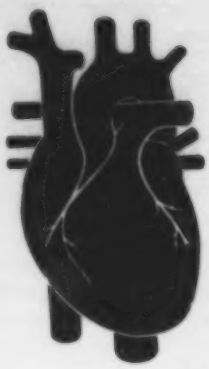
THE FIGHT AGAINST HEART DISEASE



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Part I

Diet, Exercise and Other Keys to a Healthy Heart

by Roger W. Miller

The heart is a pump. It pumps by contracting and relaxing, forcing blood on its journey to deliver oxygen and nutrients to the far reaches of the body. The pumping action occurs some 100,000 times a day. "Used" blood comes back to the heart, which circulates the liquid back to the lungs for replenishing with oxygen.

It is the muscle in the wall of the heart that does the pumping. That muscle, known as the myocardium, is like other living tissue in that it needs oxygen to function. When part of the muscle is denied oxygen, it dies; a piece of the heart is damaged and no longer contracts; the pump works less efficiently.

On popular TV programs such as "St. Elsewhere" and in real life, doctors and nurses will often refer to such a situation as a "myocardial infarction" or simply an "infarct" or, even more simply, an "M.I." (Infarction means damage.)

Most of us know an M.I. as a heart attack.

Heart attack is the largest single cause of death in the United States, accounting for 36 percent of all deaths among males aged 35 to 64.

Heart attacks may cause death almost instantaneously, or they may leave a person severely impaired. Sudden death occurs in about one-fourth of heart attack cases. Most deaths occur within two hours of the attack.

Some heart attacks are disguised. They are silent attacks, showing no symptoms. These silent attacks nevertheless leave damage and evidence that something is wrong. Electrocardiograms (EKGs) can reveal if a silent heart attack has occurred. In an EKG, the heart's electrical impulses are recorded. Variations in the impulse patterns can reveal damaged areas of the heart.

For other than silent heart attacks, the usual symptoms are tightening of the chest or chest pain (often radiating to the shoulder, arm, neck or jaw), nausea, cold sweat, and shortness of breath.

When the heart muscle doesn't get enough blood (and oxygen), it is usually because one of the arteries supplying blood has become sealed off. Such a blockage is known in medical terms as coronary occlusion or thrombosis. (Coronary refers to the heart arteries; occlusion means blockage; thrombosis is another name for a clot.)

But, once again, whether it's called a "coronary," "coronary occlusion" or "coronary thrombosis," we know it as a heart attack.

Arteries become blocked, narrowed or clotted because the inner walls are thickened or made irregular by deposits of fatty substances. Deposits usually form where artery walls are weakened. The deposits may become hardened with calcium, the rough edges becoming places for more substances in the blood to collect. These deposits, or plaques, gradually narrow the artery and thereby allow less blood to pass through. The plaque may also serve as a place for clots to form.

The process represents a degeneration, or "hardening," of the arteries. It's a process that goes on throughout life and in arteries throughout the body but, of course, when it occurs in a severe form in the heart, life is threatened.

"Can You Prevent Heart Disease?" is the title of the first chapter of the American Medical Association's excellent book *Heart Care*. That question is answered in the first sentence of the book with a quotation from the late, eminent heart specialist Paul Dudley White, M.D. Said Dr. White: "Heart disease before eighty is our own fault, not God's or Nature's will."

How we live and what we eat largely determine our susceptibility to heart attack and other heart disease. The list of do's and don'ts for heart-healthy living and eating is not long. In their book *Take Care of Your Heart*, Dr. Ezra A. Amsterdam and Ann M. Holmes say that the "Big Three" risk factors are cigarette smoking, high blood pressure, and high levels of cholesterol and triglycerides in the blood. U.S. Surgeon General C. Everett Koop notes that a person with those three risk factors is eight times more likely to have a heart attack than a person with none of them. Other risk factors for heart disease are diabetes, a family history of heart disease, obesity, lack of exercise, and stress.

Dr. Robert I. Levy, former director of the National Heart, Lung and Blood Institute, also cites the "Big Three" risk factors in a brochure, noting: "By controlling risk factors—cigarette smoking, high blood pressure, eating habits—preventive medicine we practice can have a great effect [on cutting down the chance of having a heart attack]."

A closer look at those risk factors for heart attack and other

(Continued on page 4)

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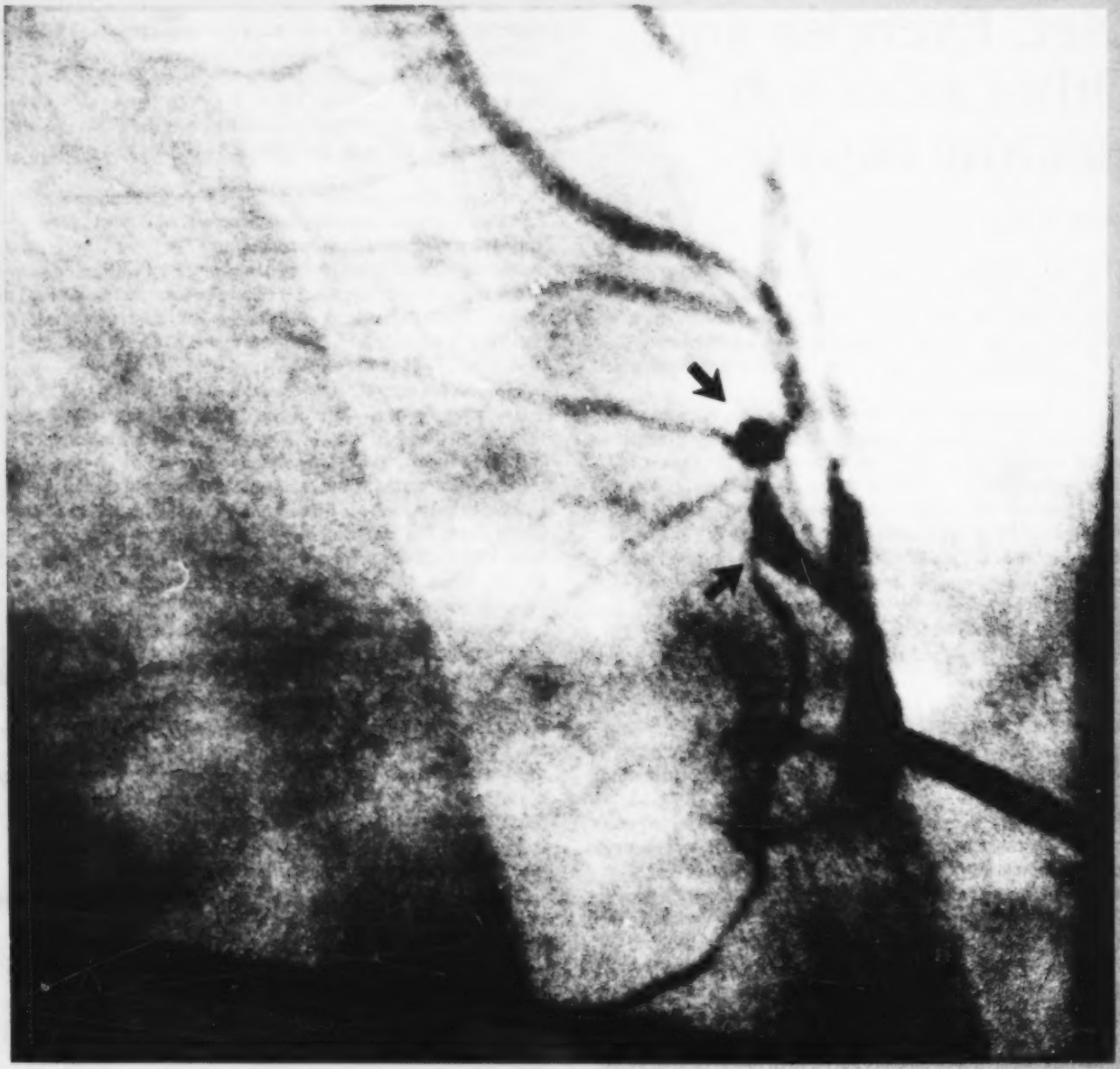
Three artery blockages in the heart of an angina patient show up as black spots in this coronary angiogram — a special X-ray that employs contrast dyes (administered by catheter) to reveal the arteries. Open heart surgery has been recommended for the patient, who is taking the drug Cardizem (generic name, diltiazem hydrochloride), a calcium-blocking agent that relaxes the blood vessels, thus increasing the supply of blood and oxygen to the heart.



The Cholesterol Connection

Cholesterol counts. Make no mistake about it. If you have high cholesterol levels in your blood, you have a greater chance of having a heart attack; eat a lot of calories, saturated fat, and cholesterol, and you're very likely to have a high blood cholesterol count.

And, according to a consensus conference held by the National Institutes of Health in December 1984, "The blood cholesterol level of most Americans is undesirably high." The experts said that high levels are due largely to too many calories and too much cholesterol and saturated fat in the diet. (Saturated fat, usually hard at room temperature, is found more often in animal products—such as meat, milk and egg yolks—than in plant products.)

Men usually have higher cholesterol counts than women. Women have more of a desirable type of cholesterol called HDLs (for high-density lipoproteins), as opposed to the villainous LDLs (low-density lipoproteins), the kind associated with heart problems. In part because of their higher HDL counts, women have about one-third the chance of developing heart disease compared to men.

Blood cholesterol levels are measured in milligrams per deciliter (a tenth of a liter, or about three ounces). Blood cholesterol levels tend to rise with age in this country, perhaps because of the large amounts of saturated fats we consume. Generally speaking, any count below 200 milligrams is considered safe; and persons 40 years and older with blood cholesterol above 260 are at high risk and should be treated. The National Heart, Lung and Blood Institute says that people with blood cholesterol over 260 have four times the risk of developing heart disease as those with a level of 190 or lower.

Public health officials are concerned that the public hasn't taken the warning about the cholesterol connection to heart, so to speak. The NIH consensus statement recommends that all Americans over the age of 2 adopt a diet that reduces fat and cholesterol intake. Health experts note that few people bother to have their cholesterol and triglyceride levels checked regularly. They would like people to know their current cholesterol levels as well as, or (for those poor in arithmetic) better than, their

checkbook balances, and they would like physicians to make measuring blood cholesterol a regular practice with their patients.

Cholesterol and triglyceride levels can sometimes be controlled by drugs. However, the side effects from the drugs are often quite bothersome. Further, an American Medical Association report recommends diet therapy be tried first, saying it is more effective. And, the report adds, "Diet therapy is generally safer than drug therapy and, when successful, may preclude it."

While diet therapy seeks to lower LDL levels in the blood, studies show that exercise helps to increase the ratio of HDLs in the bloodstream. It is believed that HDLs help rid the body of cholesterol. HDL levels are expressed in proportion to LDL levels; a ratio of at least 1 to 3 is considered desirable.

The National Heart, Lung and Blood Institute is launching a multi-million-dollar, long-term public education program to help Americans become more familiar with their blood cholesterol levels and reduce their fat and cholesterol intakes. Americans consume some 300 to 500 milligrams of cholesterol a day, down from 700 milligrams a few years ago. The experts would like to see us cut that average to no more than 300 milligrams a day. A reduction in total fat consumption is also recommended. Today we consume about 40 percent of our calories in fat. The experts want us to reduce that intake to 30 percent fat and to decrease the amount coming from saturated fat.

An analysis of diet information compiled between 1976 and 1980 by the National Center for Health Statistics gives some indication of where we get our cholesterol. The study, headed by Gladys Block, Ph.D., of the National Cancer Institute, found that one-third comes from eggs (the average egg has 270 milligrams). Other leading sources were: beef steaks and beef roasts, more than 8 percent; hamburgers, cheeseburgers and meatloaf, more than 7; whole milk and whole milk beverages, more than 5; hot dogs, ham and lunch meats, over 4 percent; and pork chops and roasts, better than 3 percent of our daily cholesterol intake.

Block and her associates figured that ground beef meals (hamburgers, cheeseburgers and meat loaf) contributed the most saturated fat to the diet (9.3 percent of the total saturated fat consumed in a day), followed closely by whole milk and whole milk products (9.1 percent). Slightly less than half the saturated fat in the diet, they calculated, came from the following foods: ground beef; milk; beef steaks and roasts; hot dogs, ham and lunch meats; doughnuts, cookies and cake; eggs; pork, including chops and roasts; and butter.

Some trade-offs are involved in a heart-healthy diet. Beef liver, for example, is high in cholesterol—440 milligrams for a 3½-ounce serving, but the American Heart Association recommends eating it at least once a month because of high levels of beneficial nutrients.

Counting the cholesterol and fat in your diet *does* make a difference. And having your blood cholesterol level measured is a simple procedure that involves taking a small blood sample for laboratory analysis. Check with your physician about having your cholesterol level checked and about what steps to take—diet changes, exercise, medications—if your cholesterol level is too high for a healthy heart. ■

heart problems brings out the reasons for the association. Here's a rundown:

- **Cigarette smoking**—The U.S. Office of Smoking and Health says there are 36 million former smokers in this country. There should be millions more. The link between smoking and heart attack and other heart diseases is established beyond a doubt. Smokers face two to four times the risk of sudden cardiac death as nonsmokers.
- **High blood pressure** (also known as hypertension)—When the pressure is high, the heart has to work harder to pump blood. High pressure indicates that the arteries are either narrow or tightened. Eating habits and exercise can affect blood pressure. Overweight people run a greater risk of high blood pressure. Likewise, sodium, which causes the blood to retain liquids, can raise blood pressure in many individuals if overused. Regular exercise is linked with lower blood pressure.
- **Cholesterol/Triglycerides**—Generally, these two substances are associated with fatty foods, such as meat, milk products, and eggs. These substances become the fatty deposits that cling to the walls of the arteries, eventually narrowing or blocking them.
- **Diabetes**—Blood vessels are damaged by diabetes, and damaged blood vessels are susceptible to hardening and subsequent narrowing. Diabetes can also lead to hypertension.
- **Family history**—We didn't get to choose our parents (if we had, we'd probably all be named Rockefeller). However, we are all subject to the genetics passed along to us, and a history of heart attacks in the immediate family can be a risk factor.
- **Obesity**—Basically, among adults, the more weight, the higher the blood pressure and cholesterol levels.
- **Exercise**—Regular exercise is good for the heart and most of the rest of the body. It helps to maintain proper weight, lower blood pressure, and may cut down on cholesterol levels.
- **Stress**—Just as regular exercise protects against heart disease, so does avoiding severe stress, the National Heart, Lung and Blood Institute says. The body reacts to stress with a complicated fight/flight syndrome. The body gets ready for action, pumping adrenalin and speeding up the heart, sending more blood to the brain and muscles. The blood pressure rises; the liver dumps cholesterol into the bloodstream.

While avoiding risk factors—to the extent possible—helps prevent heart attacks, sometimes the situation has already deteriorated to a point where the heart is already affected by lack of oxygen. Arteries may have been drastically narrowed, even blocked or clotted. In such cases, a number of steps can be taken, ranging from use of drugs as simple as aspirin to cleaning out and bypassing clogged arteries, to the ultimate therapy of a transplanted or mechanical heart operation.

Many drugs are used to treat heart problems. (See "Drugs Are Dear to Many Hearts" in the December 1981–January 1982 *FDA Consumer* and "Drugs That Block for Ailing Hearts" in the November 1983 issue.) In addition, there are drugs to treat high blood pressure, and there are medications to lower cholesterol (see "On Being Too Rich, Too Thin, Too Cholesterol Laden" in the July–August 1981 *FDA Consumer*).

Newest among the drug treatments for the heart is that old standby, aspirin. In October 1985, the Food and Drug Administration approved a labeling change for aspirin, noting that one tablet a day (5 grains, or 325 milligrams) can reduce the chances of another heart attack or death for patients who've had a heart attack or who suffer from angina pains that have been worsening, a condition known as unstable angina. Angina pains are caused by a temporary lack of oxygen for the heart. The oxygen lack may be due to a narrowed or clogged artery, and the pains are like those felt in a heart attack. But the difference between angina and a heart attack is that angina pains come and go. Intermittent or not, the pains may be an indication that a heart attack is in the future.

The role of aspirin in such situations is to lessen the likelihood of blood clotting. The studies that were conducted on aspirin involved only male patients who had suffered a previous heart attack. What effect, if any, regular doses of aspirin would have on healthy men is still being studied. The effect on women is also undetermined.

New methods for treating heart attacks include going right to the site of the clotting or blockage. In one case, a tube with an uninflated balloon-like end is inserted in a vein and directed to the site of the clotting (determined by X-rays). Pushed through the clot, the balloon is inflated and then withdrawn, opening up the clotted area in the process.

A clogged artery or arteries in the heart can call for a bypass operation. A costly operation that requires many weeks' recuperation, bypass surgery involves providing the heart with a vein from another part of the body to go around, or bypass, a clogged artery within the heart. The vein is usually taken from the leg or breast of the patient. Patients with persistent angina pains are prime candidates for bypass surgery as their angina invariably means that a blocked coronary artery is the reason the heart isn't getting enough oxygen.

The ultimate treatment for an ailing heart is replacement of the heart, with either a transplant or a mechanical heart. Bypass surgery has become almost commonplace in this country, with nearly 200,000 performed a year, but heart transplants and mechanical hearts are in their relative infancy.

Each year some 1 million heart attacks occur in this country. But the National Heart, Lung and Blood Institute reports that heart attack deaths were down 40 percent between 1963 and 1983. It seems we're learning to have a healthy heart. ■

Roger W. Miller is director of FDA's communications staff.

Heart Charts

Keeping track of cholesterol, blood pressure, and pulse rate is useful in keeping the heart healthy. Below are some charts that offer guidance on desirable ranges. Cholesterol counts are obtained by health professionals from blood samples. Blood pressure readings and pulse rates can be done at home or by a health professional. These readings are usually included in routine physical examinations, results of which are generally available to individuals.

BLOOD PRESSURE CLASSIFICATIONS

Diastolic Blood Pressure
(the lower of the two numbers)

Reading	Category
Less than 85	Normal blood pressure
85 to 89	High normal blood pressure
90 to 104	Mild hypertension
105 to 114	Moderate hypertension
115 or more	Severe hypertension

Systolic Blood Pressure
(the higher of the two numbers and coupled with a diastolic reading of less than 90)

Reading	Category
Less than 140	Normal blood pressure
140 to 159	Borderline isolated systolic hypertension
160 or more	Isolated systolic hypertension

These categories are for persons 18 and older.

Source: The 1984 "Report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure."

CHOLESTEROL

(in milligrams per deciliter)

Age	Moderate Risk	High Risk
2–19	Over 170	Over 185
20–29	Over 200	Over 220
30–39	Over 220	Over 240
40 and up	Over 240	Over 260

Source: National Institutes of Health consensus conference statement, Lowering Blood Cholesterol, *1984.*

EXERCISE PULSE RATES

Age	Target Zone
20	120–150
25	117–146
30	114–142
35	111–138
40	108–135
45	105–131
50	102–127
55	99–123
60	96–120
65	93–116
70	90–113

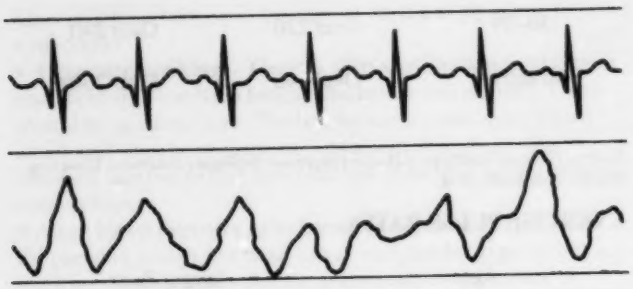
"Target zone" is the pulse or heart rate in beats per minute. Exercise that sustains that target zone level for 30 minutes should be undertaken at least three times a week. Persons over 40 who have not been exercising regularly should consult a doctor before embarking on such a program.

Source: Exercise and Your Heart, *National Heart, Lung and Blood Institute.*

Part II

Back from the Brink: New Weapons Against Cardiac Arrest

by Richard C. Thompson



Cardiac arrest can occur when the heart's electrical impulses are disrupted.

Relentless organ that it is, the heart can sometimes—through injury, accident or disease—falter and slip into a meaningless flutter called "fibrillation." Or it may stop abruptly. Cardiac arrest has occurred. No blood moves through the body. Respiration ceases, the pupils dilate, and the pulse disappears. Organs and tissue will die within minutes, beginning with the brain.

Medical scientists have long known that the pumping contractions of the heart depend on tiny electric currents generated within the heart. These currents fan out from the sinus node near the top of the heart to the four chambers (two auricles and two ventricles), causing the heart muscle to contract and pump blood through the body.

Cardiac arrest occurs when these currents are disrupted. The pulsing rhythm disappears and the blood no longer moves. Most often the cause is a heart attack (myocardial infarction) from clogged or narrowed arteries leading to or within the heart. (See "Diet, Exercise and Other Keys to a Healthy Heart," beginning on page 8.) But arrest can also result from suffocation, near drowning, drug overdose, stroke, anesthesia, electrical accidents, head injury, and other causes. Regardless of the cause, the person will die unless the heartbeat and circulation are quickly restored.

Traditionally there was little that could be done to save a person in cardiac arrest. A sharp blow to the chest might start the heart up again. If medical aid was available, adrenalin could be injected directly into the heart. The chest could be opened—a risky and hurried procedure—and the heart physically massaged. Sometimes these efforts worked, but usually the victims died.

In the early 1950s, researchers at the Johns Hopkins Hospital in Baltimore had shown that stopped or fibrillating hearts could be shocked back into action. Their findings led to development of a defibrillating machine used in hospitals and ambulances. From that bulky device there has now evolved a tiny defibrillator that can be implanted in a human being to prevent cardiac arrest, a natural development for the 1980s' decade of miniaturization.

Drug therapy can be effective for many persons with cardiac arrhythmias—interruptions in the heart's normal rhythm—that can lead to cardiac arrest. These include fibrillation and tachycardia, a wildly rapid heartbeat. There are 1.2 million people in the United States who take medication to control these conditions. A new drug (flecainide acetate) now on the market helps suppress premature ventricular contractions, which can occur in persons with heart disease in which the heart muscle contracts before the next regular beat. Unless controlled, this interruption of the heartbeat can turn into life-threatening fibrillation.

But some 400,000 persons susceptible to fibrillation or tachycardia cannot be helped by medication. The annual death rate in this group from sudden cardiac arrest has been reported to be between 30 and 60 percent.

That rate dropped dramatically—to less than 4 percent—among 400 patients with cardiac arrhythmias who participated in clinical trials of the implantable defibrillator. The astounding success of the trials led the Food and Drug Administration to approve the device in October 1985.

The new defibrillator consists of an electrical pulse generator that is about the size of a deck of cards and weighs eight ounces. It is made of titanium and other materials unaffected by body tissue and fluids and is surgically implanted in the patient's abdomen.

Within the generator are microcircuits that sense and monitor heart action and compare it with the normal rhythms stored in the device's memory.

There are three wire "leads" placed within or sutured to the heart to connect the pulse generator to the heart muscle. One is attached to the outside of the heart over the apex (high point) of the lower left chamber. The others are inserted by the surgeon through chest veins into the right chamber of the heart to monitor heart action and respond as needed to restore the heartbeat. The ends of the leads are brought along beneath the skin to the abdomen and connected to the pulse generator placed in a little tissue pocket below the waistline.

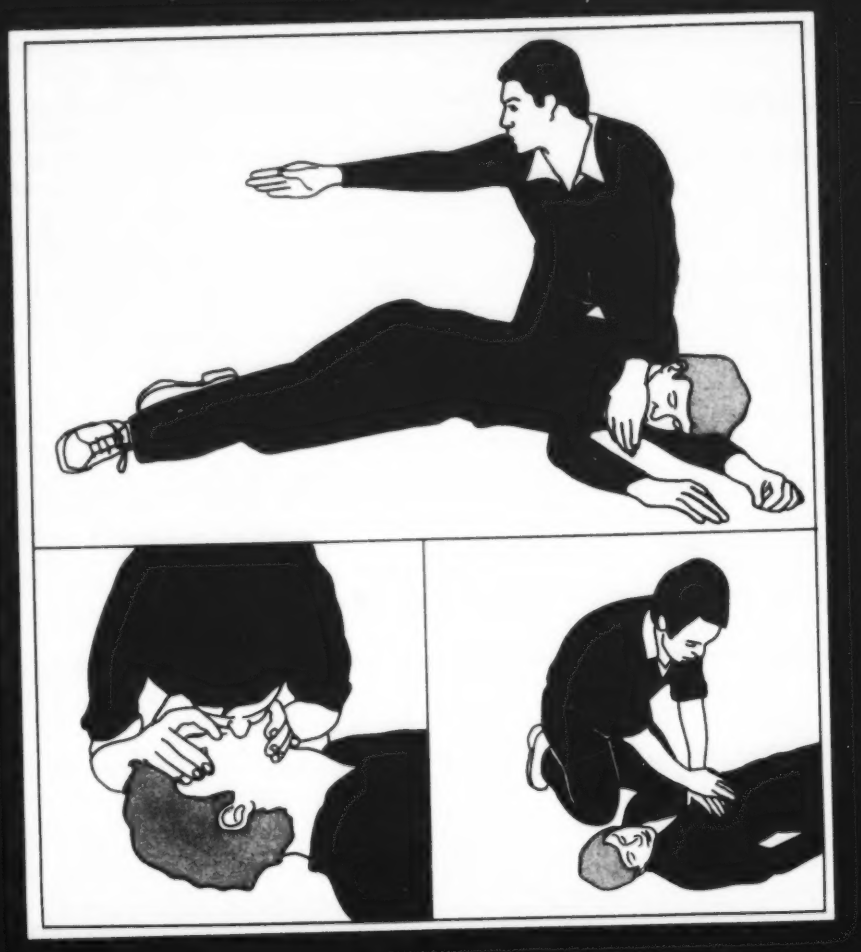
The wire leads from the heart carry continuous signals on the heart's action. When the generator receives a signal that the heart is stilled or fibrillating, it sends an automatic electrical impulse to jolt the heart back into the proper rhythm. Generally, a single shock is sufficient. If not, up to three additional shocks may be given. With the heart back in rhythm, the generator stops sending impulses, recycles, and settles down to monitoring the heart again.

Cardiac arrest victims immediately become unconscious and are not aware—when they recover moments later—that their heart had lost its beat and the defibrillator had restored it. They may feel a dull ache, as though someone had thumped them on the chest.

Both the sensing and defibrillating circuits and the battery system are derived from space-age technology. Also borrowed from the space program is a telemetry (signal-sending) circuit that allows the physician—using a special test instrument—to check the device's performance from outside the body, to determine how it is functioning and how many times it has had to shock the heart muscle.

The device can be pre-programmed by the patient's physician to allow for a normal increase in heart rate—such as could result from exercise—that the device might otherwise think is tachycardia.

The lithium battery can deliver about 100 separate impulses and should last two or three years, depending on how often it has



CPR must be administered within minutes of a person's being stricken. First, check for pulse and breathing, to be certain the person has not simply fainted. Next, call for help but do not wait for it to arrive. Position the victim on his back, tilt back the head, check that the airway is open, and begin CPR.

Until help arrives, CPR can be done by one rescuer kneeling by the victim's side, pressing down quickly and firmly on the lower chest to push blood out of the heart, then letting up so that the heart can refill. After every fifteen compressions the rescuer pauses to breathe twice into the victim's lungs.

A second rescuer kneeling on the other side can take over the ventilation breathing, giving one full breath into the victim's lungs after every five compressions by the first rescuer. The second rescuer also checks for spontaneous pulse and breathing. Rescuers can trade places as desired, since doing the compression part of CPR is tiring.

Unless a person has been stricken in a completely isolated area, it is likely that help beyond that of those first rescuers is on the way. Ambulance crews are trained and experienced in CPR and other resuscitation techniques, and their vehicles are equipped with medication, oxygen and even defibrillators. But it is those first few minutes that count the most, when the hope is that someone in the crowd gathered around the victim steps forward and says, "I know CPR."

The Lifesaver Known as CPR

In the course of their pioneering work with the defibrillator back in the 1950s, Johns Hopkins researchers discovered that blood could be moved through the body of victims of cardiac arrest by pressing firmly and forcefully on the chest. This discovery went on to become cardiopulmonary resuscitation, now used and taught throughout the world as CPR.

The technique was discovered accidentally by Guy Knickerbocker, a graduate student working with Dr. William Kouwenhoven, pioneer in using electric shock (defibrillation) to jolt a stopped or quivering heart back into action.

As professor of electrical engineering at Johns Hopkins, Kouwenhoven had long been interested in the effects of electricity on the human body. He had shown that an electric current applied directly to the heart could restore the heartbeat, but this required opening the victim's chest. Kouwenhoven set about developing a defibrillator that could be used to shock the heart from outside the chest. By 1957, he had perfected the device, a small box cabinet with two insulated cables. It became standard equipment at the Johns Hopkins Hospital and elsewhere for use in cardiac arrest.

Knickerbocker continued his experiments with the defibrillator. One day in 1958 he noticed that simply placing the heavy copper electrodes on the chests of anesthetized animals caused the blood pressure to rise. Pressing down with the electrodes made it rise even higher.

From this, he and others in the Hopkins group, including cardiac surgeon Dr. James Jude, surmised that forceful, rhythmic pressure on the chest could—in a stilled or fibrillating heart—cause enough blood to move through the body to sustain the vital organs. A year of testing showed that they were right: Closed-chest massage could maintain up to 40 percent of normal circulation.

Satisfied that it worked, the group announced its discovery. Within months it was combined with mouth-to-mouth resuscitation (another technique perfected at Hopkins) to become cardiopulmonary resuscitation, now known as CPR. ■

been called on to deliver a restorative shock. It can be replaced as needed through minor abdominal surgery.

The defibrillator is intended for persons who have suffered cardiac arrest or episodes of tachycardia or fibrillation that cannot be reversed or controlled by medication or surgery. It is not suitable for those who have frequent or recurring episodes that would soon deplete the batteries. Also, it should not be implanted in persons who already have cardiac pacemakers since the two may interact.

(Pacemakers are different from the implantable defibrillator in that they help the heart maintain a proper rate of beating. They cannot control tachycardia nor jolt a stopped or fibrillating heart back into action. For more about pacemakers, see "Cardiac Pacemakers: Keeping Up the Beat" in the July-August 1980 *FDA Consumer.*)

The implantable defibrillator was developed by Dr. Mieczyslaw Mirwoski, associate professor of medicine at the Johns Hopkins Medical Institutions, and by Intec Systems of Pittsburgh, Pa. The device's circuitry and power source were extensively tested in the laboratory before beginning five years of testing with animals. In one series of animal tests, the device detected all episodes of heart arrhythmias and corrected almost 90 percent of them, usually with a single shock.

Clinical studies with human patients, begun in 1980, were similarly successful; the device was able to detect the onset of ventricular tachycardia and fibrillation and to restore normal heart rhythms.

One physician who took part in the trials said that fibrillation patients who have had a single episode of cardiac arrest have a 40 percent chance of a second episode within a year, and that such patients equipped with the device "have a very good safety net."

The new device is expensive, costing $15,000 for the pulse generator and about $500 for each of the two or three leads, plus surgical fees for the hour-long implant operation. That cost is expected to come down in the future. ■

Richard C. Thompson is a member of FDA's public affairs staff

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